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Systematic Review

Safety and side effects of acupuncture therapy in Australia: A systematic review

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ABSTRACT

Introduction: The tremendous popularity of acupuncture in Australia demands continual safety assessment. This review aimed to determine the characteristics of acupuncture related adverse events, analyse their possible causes, and inform future research and practice.

Methods: Across 8 databases, all types of clinical trials, surveys, and case reports from 2012 to 2018 reporting adverse events associated with the use of acupuncture in Australia on human subjects were systematically reviewed. Types of acupuncture including manual acupuncture, electro acupuncture and laser acupuncture. Incidence and form of acupuncture related adverse events were the key outcomes of this study. In addition, the quality of adverse events reporting and the likelihood of causality were examined by two reviewers and checked by two experts specialised in acupuncture.

Results: The 17 analysed studies encompassed ten randomised controlled trials, two nonrandomised controlled trials, three uncontrolled clinical trials, and two case reports, with a total of 1160 participants receiving true acupuncture. Feelings of dizziness, fatigue and nausea were the most common adverse events identified in our review across all acupuncture modalities.

Conclusions: Acupuncture is generally a safe modality and serious adverse events after treatment are uncommon when supported with well-established guidelines and practiced by licensed, qualified practitioners.

1. Introduction

Practiced for more than 4000 years, acupuncture is an essential part of Traditional Chinese Medicine (TCM) [1] and plays a vital role in the healthcare of Chinese people. Huang Di Nei Jing (The Yellow Emperor's Internal Classic), the first and most extensive medical work existing in China [2] signifies that acupuncture has developed into a unique and indispensable therapy in Chinese medicine.

TCM believes that acupuncture brings the imbalanced (diseased) body back into balance [2] by restoring the balance of Yin and Yang, reinforcing the vital Qi and eliminating pathogenic factors, regulating the functions of Zang Fu and circulating the Qi and Blood of the body.

Acupuncture has become the most popular complementary and alternative therapy in Australia over the last 20 years [3–5]. Studies have demonstrated that acupuncture therapy can serve as a promising treatment modality [1,6–12], for instance, acupuncture is widely used in chronic pain management [13]. The framework underlying this modality is fundamentally holistic and provides an interesting model for health professionals who seek different ways to approach health care and improve patient outcomes [14].

Registration to practice acupuncture in Australia is mandatory and an 'acupuncturist' is a protected title under the new Registration Law. Currently there are nine existing bachelor degree and one master degree programs which have been approved to meet educational requirements for registration. By December 2017, there were 4905 registered practitioners in Australia. [14,15]. Despite its strict regulation to practice acupuncture in Australia, the safety of performing such a modality is lacking clinical evidence. To date, no study has evaluated the adverse events associated with acupuncture in Australia. This systematic review aimed to determine the characteristics of acupuncture related adverse events, analyse their possible causes, and inform future research and practice, therefore enhance safe practice within the profession.

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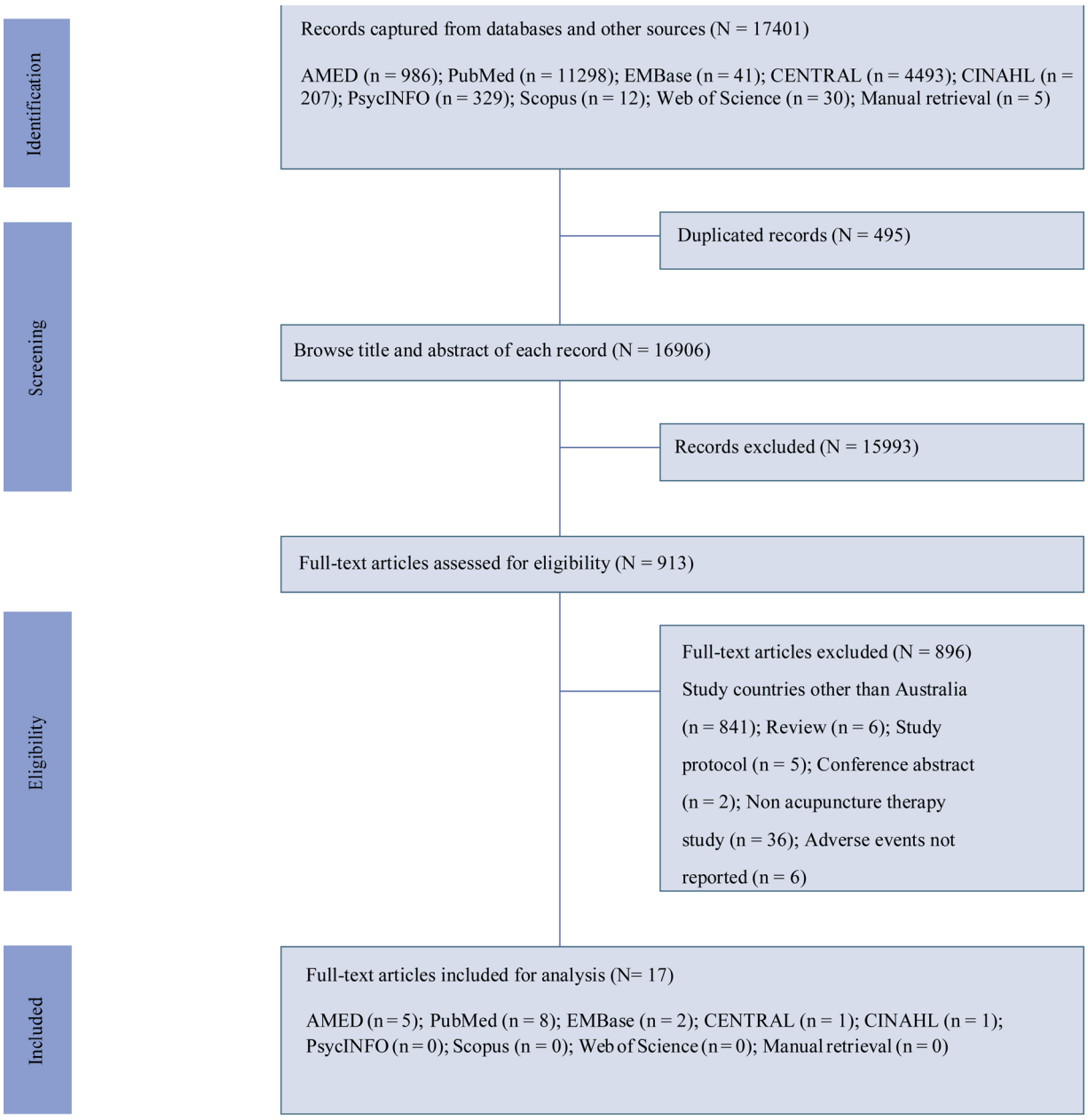

Fig. 1. Flow chart of study selection.
Note: AMED: Allied and Complementary Medicine, EMBase: Excerpta Medica database, CENTRAL: Cochrane Central Register of Controlled Trials, CINAHL: Cumulative Index to Nursing and Allied Health Literature.

2. Methods

2.1. Definition

In this study, an adverse event was defined as an undesirable experience associated with the use of a medical product on a patient [16].

2.2. Inclusion and exclusion criteria

All types of human clinical trials, surveys, case reports, and case series occurring in Australia which reported an adverse event associated with acupuncture were included. Types of acupuncture included: manual acupuncture, electro acupuncture and laser acupuncture. Manual acupuncture inserts needles into acupoints followed by the twisting of the needle with different manual strengths, electro acupuncture applies a stimulating current to acupoints via the inserted needles, whereas laser acupuncture uses laser light on acupoints instead of needles.

2.3. Data sources and searching strategies

From 1 July 2012, in order to practice in Australia, acupuncture practitioners must be registered under the national registration body—the Chinese Medicine Board of Australia and meet the Board's Registration Standards [15]. For this reason, only studies from 2012 to 2018 were included in this review. Relevant studies were captured from 8 electronic databases, manual search, and a reference lists search. These databases including Allied and Complementary Medicine (AMED), PubMed, Excerpta Medica database (EMBase), Central Register of Controlled Trials (CENTRAL), Cumulative Index to Nursing and Allied Health Literature (CINAHL), PsycINFO, Scopus, and Web of Science. Studies conducted in Australia and written in English were the

Table 1
Adverse events associated with acupuncture therapy reported in case reports.

Study and setting	Age (Gender)	Reason for AT	Type of AT (method and duration)	Practitioner	Selected acupoints	AEs and severity	Outcomes	Causality*
(Chia, 2015) [20] Clinic, Adelaide, Australia	62 (female)	Symptomatic tarlov cyst	Method: electro acupuncture Duration: 25 minutes each session for 2 sessions in 2 weeks	Not reported	1st session: Shenshu BL 23, Qihaishu BL 24, Dachangshu BL 25, Guanyuanshu BL 26, Zhishi BL 25, Huantiao GB 30, Yaoyangguan GV 3, and Mingmen GV 4 2nd session: Biolateral BL 28 were added to the initial treatment regimen.	Event(s): mild right-sided sciatica, and then disabling severe buttock pain (8/10) which was suggestive of symptomatic tarlov cyst	The symptoms decreased to a moderate level (5/10) after two days of bed rest. The pain had returned to the initial condition before the attack (3/10) two weeks later	Possible
Robinson, Lind, Smith, & Kodali, 2016 [21] General hospital, Perth, Western Australia	67 (male)	Cervical spondylosis	Method: acupuncture Duration: 5 weeks	Not reported	Not reported	Event(s): Atlanto-axial infection Severity: Laboratory tests and MRI confirmed septic arthritis of the atlanto-axial joint	Recovery after a course of intravenous antibiotics	Possible

AT: acupuncture therapy, AE: adverse event, and TCM: traditional Chinese medicine.
Causality*: The WHO-Uppsala Monitoring Centre (UMC) System for Standardized Case Causality Assessment [19]: certain—a plausible time relationship that AEs clearly occurred after receiving AT and disappeared after withdrawal, and these events could not be explained by other health problems or interventions; probable/likely—a reasonable time relationship that the onset of symptoms was most likely related to AT and that was unlikely attributed to other health problems or interventions; possible—a reasonable time relationship that the onset of symptoms was most likely related to AT but that could also be explained by other health problems or interventions, and the information at withdrawal was lacking or unclear; unlikely—there was an improbable time relationship between AT and the AE; conditional/unclassified—event occurred but more data were essential for a proper causality assessment; unassessable /unclassifiable—an AE was suggested by a report but cannot be judged due to insufficient or contradictory information.

restrictions applied for the search. Reference lists of the included papers were also checked to identify the potential eligible studies. All searches were conducted by two reviewers (CC Wang and JY Tan) independently. Keywords and Medical subject Headings (MeSH) were used to identify relevant literature. The search strategy comprised of acupuncture specific terms such as (“acupuncture” OR “acupuncture therapy” OR “acupuncture treatment” OR “acupuncture points” OR "electro acupuncture", OR "laser acupuncture", etc.) and condition specific search terms such as (“adverse event*” OR “side effect*” OR “adverse effect*” OR "adverse health care event*" OR “safe” OR "risk*").

2.4. Study selection and data extraction

For each included paper, the characteristics of study (authors, year of publication, design, and setting), participant (age, gender, sample size, diagnostic criteria, and reason for acupuncture), intervention (types of acupuncture, practitioner, selected acupuncture points, treatment duration), and adverse event (type of adverse events, frequency, outcome, and causality) were extracted. Study selection and data extraction were conducted by two reviewers independently, and disagreement was resolved through discussion.

2.5. Outcome assessment

Characteristics of acupuncture related adverse events and their possible causes were the key outcomes of this study. In addition, the quality of adverse events reporting and the likelihood of causality were examined by two reviewers and checked by two experts specialized in acupuncture.

The quality of adverse events reporting for clinical trials was appraised using the *CONSORT for Harms Data Recommendations* [17,18]. The likelihood of causality for adverse events reported in case reports or case series, was appraised by the *WHO Uppsala Monitoring Centre (UMC) System for Standardized Case Causality Assessment* [19].

3. Results

3.1. Characteristics of analysed studies

Searches (electronic and manual) yielded 17,401 records. 495 duplicated records were removed after scanning by reference management software (Endnote), and another 15,993 were further excluded after inspecting the titles and abstracts. Full text of the 913 remaining records was captured for eligibility assessment, and 896 articles were finally excluded due to study countries were other than Australia (n = 841)—despite the fact that we set the restriction of particular country as ‘Australia’ when performing the database search), reviews (n = 6), study protocols (n = 5), conference abstracts (n = 2), non-acupuncture therapy interventions (n = 36), and the adverse events were not reported (n = 6). Therefore17 studies [20–36] were identified for final analysis. The study selection flow chart is presented in Fig. 1.

The analysed studies encompassed 10 randomised controlled trials, two nonrandomised controlled trials, three uncontrolled clinical trials, and two case reports, with a total of 1160 participants receiving true acupuncture. These studies were all from Australia. Four acupuncture modalities were employed including manual acupuncture [21,23,25,28–31,33–36], laser acupuncture [22,24,25,27,31,32], and electro acupuncture [20,26,36]. Acupuncture was performed in these studies to manage a range of health problems such as symptomatic tarlov cyst, cervical spondylosis, depression, breast cancer, anorexia nervosa, pain, nausea, and allergic rhinitis.

Within the 15 clinical trials (randomised controlled trials, non-randomised controlled trials, and uncontrolled clinical trials), nine studies reported a significantly positive effect of acupuncture for the primary and/or secondary outcomes between groups [22–25,27,32–34,36], while six studies only detected favorable changes

Table 2
Adverse events associated with acupuncture therapy reported in clinical trials.

Study	Reason for AT and practitioner	Intervention (details of AT) and control	Selected acupoints	AEs (number of cases) of AT and outcome	Quality of AEs reporting
(Quah-Smith, Sachdev, Wen, Chen, & Williams, 2010) [22] Hospital, Sydney, Australia	R: Brain effects in healthy individuals P: acupuncturist	Intervention: Laser acupuncture 1) Method: 100 mW low intensity infra-red (808 nm) laser. 2) Duration: 20 seconds at each acupoint with alternating laser 'on' and laser 'off', 4 times for each acupoint Control: non acupoint (sham point)	Right side LR 14, CV 14, left side HT 7, and left side LR 8	Participants: (n = 10) AEs: Minimal uncomfortable (n = 1) (From Intervention group) Outcome: no major AEs occurrence	1 Not reported 2 Inadequate 3 Not reported 4 Not reported 5 Not reported 6 Not reported 7 Partially adequate
(Lyons, Watt, Shen, & Janca, 2012) [23] Clinic, Perth, Western Australia	R: depression P: acupuncturist	Intervention (true AT): 1) Method: acupuncture (needles: size 0.25*30 mm) 2) Duration: 30 min per session, twice per week for 5 weeks Control: True AT + herbs to take 3 times a day	Touwei (ST8), Yintang, Quchi (LI11), Waiguan (TE5), Hegu (LI4), Qihai (CV6), Yinlingquan (SP9), Sanyinjiao (SP6), Zusanli (ST36), Yanglingquan (GB34), Taichong (LR3), Fenglong (ST40)	Participants: (n = 19) (Intervention group n = 12; Control group n = 7) AEs: painful (n = 9) (From both groups) Outcome: well tolerated	1 Not reported 2 Not reported 3 Not reported 4 Not reported 5 Not reported 6 Not reported 7 Partially adequate
(Quah-Smith, Wen, Chen, Williams, & Sachdev, 2012) [24] Research institute, Sydney, Australia	R: Brain effects in depressed individuals P: acupuncturist	Intervention: Laser acupuncture 1) Method: 100 mW low intensity infra-red (808 nm) laser. 2) Duration: 24 seconds at each acupoint with alternating laser 'on' and laser 'off', 4 times for each acupoint	Right side LR 14, CV 14, left side HT 7, left side LR 8, and right side KI 3	Participants: (n = 10) AEs: Minimal adverse effect profile Outcome: no major AEs occurrence	1 Inadequate 2 Inadequate 3 Not reported 4 Not reported 5 Not reported 6 Not reported 7 Inadequate
(Quah-Smith, Williams, Lundeberg, Suo, & Sachdev, 2013) [25] Clinic, Sydney, Australia	R: investigate the differential brain effects of needle acupuncture and laser acupuncture at LR8 P: acupuncturist	Intervention A (needle AT): 1) Method: manual acupuncture (needles: size 0.22*25 mm) 2) Duration: typical of manual acupuncture while undergoing MRI acquisition Intervention B (laser AT): 1) Method: laser acupuncture (Euryphaessa AB, Stockholm, Sweden, 808 nm) 2) Duration: the laser session according to the time signal while undergoing MRI acquisition	Ququan (LR8)	Participants: (n = 16) AEs from both groups: Needle AT: very mild pain and unwell (n = 16) Laser AT: very mild transient tiredness and dizziness, vagueness and nausea (n = 16) Outcome: very mild. None required medical interventions	1 Not reported 2 Not reported 3 Not reported 4 Not reported 5 Not reported 6 Not reported 7 Adequate
(Oh et al., 2013) [26] Hospital, Sydney, Australia	R: arthralgia secondary to aromatase inhibitor therapy in women with early breast cancer P: acupuncturist	Intervention (true AT): 1) Method: electro acupuncture on standard body points (needles: size 0.20*25 mm) 2) Duration: 20 min per session, 2 sessions a week for 6 weeks Control: sham electro acupuncture	Standard body points: LI 4, LI 11, GB 34, ST 40, LR 3, GV 20, *shishencong* and *Baxie* on day 1 GB 21, TE 5, ST 36, SP 6, LR 3, GV 20, shishencong and Baxie on day 2	Participants: (n = 29) (Intervention group n = 14; Control group n = 15) AEs: Minor bruising on acupuncture points (n = 5) (From both groups) Outcome: no major AEs occurrence	1 Adequate 2 Not reported 3 Not reported 4 Inadequate 5 Not reported 6 Inadequate 7 Partially adequate
(Quah-Smith, Smith, Crawford, & Russell, 2013) [27] A private acupuncture clinic, Sydney, Australia	R: depression P: acupuncturist	Intervention: Laser acupuncture 1) Method: 100 mW low intensity infra-red (808 nm) units were produced. 2) Duration: 10 seconds to deliver one joule of laser energy at each acupoint, a total of 5 J for 5 acupoints per session, twice a week for 4 weeks and once a week for another four weeks, for a total of 12 sessions Control: Placebo laser	Right side Qimen LR 14, Juque Ren 14, left side Ququan LR 8, left side Shenmen HT 7 and right side Taixi KI 3	Participants: (n = 43) (Intervention group n = 22; Control group n = 21) AEs: Minimal transient fatigue (From both groups) Outcome: no major AEs occurrence	1 Adequate 2 Inadequate 3 Inadequate 4 Adequate 5 Not reported 6 Not reported 7 Not reported
(Smith, Pirotta, & Kilbreath, 2014) [28] Clinic, Sydney, Australia	R: reduce symptoms of lymphoedema after breast	Intervention (true AT): 1) Method: acupuncture on non-affected arm (needles: size 0.20*30 mm)	Selected three standardised points from the following: Zhongwan (CV12), Zhongji (CV3), Qugu (CV2); Jianyu (LI15), Yangchi (TE4), Chize (LU5), Yangxi	Participants: (n = 17) (Intervention group n = 9; Control group n = 8) AEs:	1 Partially adequate

(*continued on next page*)

Table 2 (*continued*)

Study	Reason for AT and practitioner	Intervention (details of AT) and control	Selected acupoints	AEs (number of cases) of AT and outcome	Quality of AEs reporting
	cancer P: acupuncturist	2) Duration: 20 min per session, 12 treatments over 8 weeks Control: Treatment as usual	(LI5); Zusanli (ST36), Yinlingquan (SP9), and Sanyinjiao (SP6) Other acupuncture points were used based on the individual diagnosis	uncomfortable (n = 1) (From intervention group) Outcome: no major AEs occurrence	2 Partially adequate 3 Partially adequate 4 Partially adequate 5 Adequate 6 Partially adequate 7 Partially adequate
(Smith et al., 2014) [29] Private hospital, Sydney, Australia	R: for patients with anorexia nervosa P: acupuncturist	Intervention (true AT): 1) Method: acupuncture (needles: size 0.22*30 mm) 2) Duration: 20 min per session, 9 treatments over 6 weeks Control: Acupressure and massage	Hegu (LI4), Zusanli (ST36), Neiguan (PC6), Taichong (LR3), Yanglingquan (GB34); And additional points based on the individual TCM diagnosis	Participants: (n = 20) (Intervention group n = 10; Control group n = 10) AEs: Mild uncomfortable (n = 1) (From intervention group) Outcome: well tolerated	1 Not reported 2 Not reported 3 Not reported 4 Partially adequate 5 Not reported 6 Not reported 7 Inadequate
(Zhang, Parker, Taylor, & Xue, 2014) [30] Hospital ED, Melbourne, Australia	R: for ED patients with pain and nausea P: acupuncturist	Intervention (true AT): 1) Method: acupuncture (needles: size 0.25*30 mm) 2) Duration: 20 min per session Control: Usual care	Individualised points based on TCM diagnosis	Participants: (n = 400) (Intervention group n = 200; Control group n = 200) AEs from intervention group: Slight bleeding (n = 2) Mild pain at the needling sites (n = 2) Outcome: no major AEs occurrence	1 Partially adequate 2 Partially adequate 3 Not reported 4 Not reported 5 Not reported 6 Adequate 7 Adequate
(Hinman et al., 2014) [31] Community, Melbourne, Australia	R: chronic knee pain P: acupuncturist	Intervention (true AT): A group: needle B group: laser C group: sham laser protocol (ACTRN12609001001280) Control: No acupuncture	Points based on the protocol (ACTRN12609001001280)	Participants: (n = 282): Intervention groups n = 211 (Group A: n = 70; Group B: n = 71; Group C: n = 70) Control group n = 71 AEs: mild and transient pain (n = 2) (From intervention groups) Outcome: no major AEs occurrence	1 Partially adequate 2 Not reported 3 Not reported 4 Inadequate 5 Not reported 6 Inadequate 7 Inadequate
(Glazov, Yelland, & Emery, 2014) [32] 6 GP clinics, Perth, Australia	R: Chronic low back pain P: General practitioners (GPs)	Intervention: laser acupuncture 1) Method: laser machines (20 mW, 840 nm diode, power density 0.1 W/cm^2) stimulated points in two treatment groups: low dose (02 J/point) group with 10 seconds per point and high dose (0.8 joules/point) group with 40 seconds per point 2) Duration: 15 min per session, 1 session a week for 8 weeks Control: sham (0 joules/point)	Acupuncture point selection was individualised for each patient. Tender regional and more distal points along radiation pathways of pain were selected. Other acupuncture points depending on additional symptoms reported (e.g. headache, other joint pain and psychological issues) were selected at the discretion of the therapist. An average of about nine points were used per session.	Participants: (n = 144): Intervention groups n = 96 (Low dose group n = 48; High dose group n = 48) Control group n = 48 AEs: mild and transient pain (n = 1) (From intervention groups) Outcome: no major AEs occurrence	1 Not reported 2 Not reported 3 Not reported 4 Inadequate 5 Not reported 6 Not reported 7 Inadequate
(Wang, Xue, Helme, Da Costa, & Zheng, 2015) [33] Clinic, Melbourne, Australia	R: frequent migraine P: acupuncturist	Intervention (true AT): 1) Method: acupuncture (needles: size 0.25*30/40 mm) 2) Duration: 25 min per session, 16 sessions during 20 weeks Control: sham AT: combined insertion and noninsertion technique, sham point (1-2 cm away from the real acupoints)	Mandatory acupoints: Fengchi (GB20), Taiyang (EX-HN5), Shuaigu (GB8), Hegu (LI4), and points on the side of current migraine, or points on the side of the last migraine episode, if no current migraine	Participants: (n = 50) (Intervention group n = 26; Control group n = 24) AEs from both groups: Dizziness (n = 4) Bruising (n = 3) Pain (n = 3) Cold and sweaty (n = 8) Tingling (n = 11) Recurrent headache (n = 7)	1 Partially adequate 2 Partially adequate 3 Not reported 4 Partially adequate 5 Not reported 6 Adequate

(*continued on next page*)

Table 2 (*continued*)

Study	Reason for AT and practitioner	Intervention (details of AT) and control	Selected acupoints	AEs (number of cases) of AT and outcome	Quality of AEs reporting
				Mild spasm in the calf muscle induced by tapping on the thigh by the patients after the treatment (n = 1) Outcome: mild or moderate. None required medical interventions	7 Adequate
(Xue et al., 2015) [34] Research institute clinic, Melbourne, Australia	R: seasonal allergic rhinitis P: acupuncturists	Intervention (true AT): 1) Method: acupuncture (needles: size 0.22*30 mm) 2) Duration: 20 min per session, 12 sessions during 4 weeks Control: sham acupuncture	• The key acupoints for all participants: Yingxiang LI 20 bilateral, Yintang MH-N 3, Fenchi GB 20 bilateral, and Hegu LI 4 bilateral • Additional individualised points: Taiyuan LU 9 bilateral for lung qi deficiency; Zusanli ST 36 bilateral for spleen deficiency; and Qihai CV 6 for kidney deficiency syndrome.	Participants: (n = 175): (Intervention group n = 88; Control group n = 87) AEs from both groups: 1) Mild or moderate pain, bruise, sensitive, numbness and weakness, tired, and nauseous. (n = 88) Outcome: no major AEs occurrence	1 Adequate 2 Partially adequate 3 Inadequate 4 Adequate 5 Inadequate 6 Inadequate 7 Adequate
(Cohen et al., 2017) [35] Two public hospital EDs and two private hospital EDs, Melbourne, Australia	R: analgesia in ED P: acupuncturist	Intervention (true AT): manual acupuncture protocol (ACTRN12609000989246) Control A: True AT + pharmacotherapy Control B: Pharmacotherapy alone	Points based on the protocol (ACTRN12609000989246)	Participants n = 528: Intervention groups n = 177; Control groups n = 351 (Control group A n = 178; Control group B n = 173) AEs from Intervention and Control group A: Rated from 0 (no impairment) to 10 (intolerable) Outcome: 73 (51%) felt from 'no impairment' to 'intolerable'.	1 Partially adequate 2 Partially adequate 3 Partially adequate 4 Adequate 5 Not reported 6 Inadequate 7 Inadequate
(Armour, Dahlen, Zhu, Farquhar, & Smith, 2017) [36] Research institute clinics, Sydney, Australia and Auckland, New Zealand	R: Primary dysmenorrhea P: acupuncturists	Intervention: 1 Low frequency manual acupuncture (LF-MA) 2 High frequency manual acupuncture (HF-MA) 3 Low frequency electro acupuncture (LF-EA) 4 High frequency electro acupuncture (HF-EA) 5 Method: MA: (needles: size 0.20*30 or 0.25*40), stimulated by hand using tonifying, reducing or even method; EA: ITO ES-160 electro-acupuncture machine, 2Hz/100Hz square wave 6 Duration: 20 minutes session, 12 sessions over the course of three menstrual cycles	Points based on the protocol (ACTRN12613000351718)	Participants: (n = 74): Low frequency manual acupuncture group n = 19 High frequency manual acupuncture group n = 18 Low frequency electro acupuncture group n = 18 High frequency electro acupuncture group n = 19 AEs from all groups: 1) Minor bruising, post-treatment soreness, and fatigue (n = 52) Outcome: no major AEs occurrence	1) Not reported 2) Not reported 3) Not reported 4) Not reported 5) Not reported 6) Inadequate 7) Adequate

AT: acupuncture therapy, AE: adverse event, RCT: randomized controlled trial, R: reason for AT, P: practitioner, and TCM: traditional Chinese medicine.
Reporting* The CONSORT Recommendation for AEs [17]: (1) report of data on harms in the title or abstract, (2) report of AT related harms in the introduction section, (3) prespecification of potential AEs of AT (clinical and/or laboratory), (4) specification of approach for collecting harms related information, (5) description of plans for presenting and analysing AEs of AT, (6) description of participant withdrawals due to AEs of AT, and (7) report of the particular denominations for analyses on AT related harms. Quality grades for each item: adequate—item was properly described in details in the article or in the study protocol; partially adequate—item was properly described but only in a brief format; inadequate—item failed to be properly described; not reported—item was not described.

within the acupuncture groups [26,28–31,35]. In these studies, the person who performed acupuncture including acupuncturist (14) and general practitioner (1).

3.2. Case reports

Two cases were identified and the disclosed adverse events were mild right sided sciatica and then disabling severe buttock pain in one case [20], and atlanto-axial infection in another case [21] (Table 1). The symptoms were decreased in the first case after two days of bed rest, whereas the second case was treated with a course of intravenous antibiotics. Electro acupuncture was used in the first case whereas the second case was manual acupuncture. Both cases failed to specify the practitioners who administered acupuncture and adverse events described in these cases were assessed as *possibly* related to acupuncture.

3.3. Clinical studies

All acupuncture related adverse events reported in clinical trials are presented in Table 2. The overall outcomes for the quality of adverse events reporting were not optimal. Eight studies adequately or partially adequately described AE in the title and/ or abstract (53%), while there were only five studies adequately or partially adequately described safety issues of acupuncture in the introduction and specification of approach for collecting harms related information (33%). Only two studies adequately or partially adequately pre specified approaches for collecting harms related information (13%), whereas only one study adequately described plans for presenting and analyzing adverse events of acupuncture (6%). Only three studies adequately or partially adequately described participant withdraw due to adverse events associated with acupuncture (20%) however there were nine studies adequately or partially adequately reporting the particular measures for analyses on adverse events related harms (60%).

3.3.1. Manual acupuncture related adverse events

Manual acupuncture related adverse events were reported in 11 clinical trials [21,23,25,28–31,33–36], with a total of 831 participants receiving acupuncture (Table 2). Except one case [21] which failed to specify the practitioners who administered acupuncture, acupuncture was performed by acupuncturists in all other studies. The most frequently reported adverse events were pain, bruising, dizziness, discomfort at the needling site, local bleeding, fatigue, nausea and inflammation at insertion. Only one patient in the case report [21] received a course of intravenous antibiotics for infection, and its adverse events was appraised as *possibly* related to acupuncture, the remaining ten studies [23,25,28–31,33–36] did not take any measures to decrease adverse events as they were transient, minor, and tolerable.

3.3.2. Laser acupuncture related adverse events

Laser acupuncture related adverse events were reported in 6 clinical studies [22,24,25,27,31,32], with a total of 213 participants receiving acupuncture (Table 2). Except for one case [32] where the acupuncture was administered by general practitioners, acupuncture was performed by acupuncturists in all other studies. The most frequently reported adverse events were mild pain, tiredness, dizziness, and nausea. None of those studies took any measures to manage adverse events as they were transient, minor, and tolerable.

3.3.3. Electro acupuncture related adverse events

Electro acupuncture related adverse events were reported in 3 clinical studies [20,26,36], with a total of 67 participants receiving acupuncture (Table 2). Except one case [20], which failed to specify the practitioners who administered acupuncture, acupuncture was performed by acupuncturists in the other two studies. The most frequently reported adverse events were minor bruising, post treatment soreness and fatigue and did not require any measure to decrease adverse events as they were transient, minor, and tolerable. However, one patient in a case report [20] experienced mild right sided sciatica and then disabling severe buttock pain, the symptoms decreased after two days of bed rest. However, the adverse events in this case report was appraised as *possibly* related to acupuncture.

4. Discussion

Our findings suggest that acupuncture has a very low rate of adverse events when conducted among licensed, qualified practitioners in Australia, and serious adverse events after acupuncture are uncommon. This conclusion is in line with recent two systematic reviews from Hong Kong and China respectively [37,38], and two surveys from Germany and the United Kingdom [39,40].

Dizziness, fatigue, nauseous, mild pain and bruising were the most common adverse events identified in our review across all modalities (manual acupuncture, laser acupuncture, and electro acupuncture). These symptoms were also found in previous reports [37–40].

These adverse events relating to mild fainting symptoms of acupuncture maybe due to transient hypotension: as acupuncture stimulation through the peripheral nerves that could dilate the peripheral blood vessels, reduce venous return, and decrease blood supply in the brain therefore causing dizziness [41,42]. These symptoms were often seen in people on their first acupuncture treatment especially for those who felt anxious or nervous before acupuncture [43].

Comparing our findings with the previous literature [37–40] which identified that infections, pneumothorax, organ and tissue injuries were the majority of the adverse events, it seemed that acupuncture practice in Australia is well regulated with better outcomes—less serious adverse events related to acupuncture. In the last 20 years, acupuncture has experienced a rapid growth in its research, education and practice in Australia. According to its regulation, “acupuncturist” is a protected title and a minimal requirement for registration in Australia is a 4 years bachelor’s degree from an accredited university. In our review, only one case report [21] indicated a moderate adverse event (infection) however, the case report was appraised as *possibly* related to acupuncture, further, the report failed to specify the practitioners who administered acupuncture. Any medical intervention has the potential to cause damage, particularly when administered by an untrained or unqualified practitioner, or in an unregulated setting. Compliance with the Chinese Medicine Board infection prevention and control guidelines, the strict hygienic procedures during acupuncture practiced by licenced acupuncturists in Australia could be one of the reasons for the low prevalence of infection discovered in our review. Nevertheless, acupuncturists need to vigilantly use this approach on clients with poor would healing capacity, such as patients with immunocompromised disorders, or diabetes mellitus [44], as potentially this could result in some none healing wounds or systemic infections.

4.1. Limitations

As the journal reviewer rightfully pointed out, to determine the incidence of adverse events for Australian practice would require a large prospective survey, as with those in the UK and Germany in the past. Small participant sample sizes in this review is one of the limitations that could affect the strength of the evidence concluded from our findings. Case reports most likely will only cover serious or unusual adverse events, which is valuable, but not informative about adverse events as a whole. The clinical trials may report on the whole range of adverse events but they can only provide estimates of incidence within each study, not for general practice. Trials by their very nature are not the same as usual practice. In this case, none of the trials were for the most frequently presented conditions (musculoskeletal, chronic pain) for acupuncture practice. Quality of adverse events reporting included in clinical trials was overall unsatisfactory which makes it difficult to evaluate the causality of adverse events reported in clinical trials.

Furthermore, we found a great number of papers not including adverse events as the study outcome, as such, acupuncture related adverse events perhaps were underreported. This review only included studies that were conducted in Australia and this itself may limit the generalisability of these findings.

5. Implications for future research and practice

Although serious adverse events associated with acupuncture are rare, acupuncture practice is not risk free, and clinical practice guidelines can minimise any risk [45]. We recommend that acupuncture should only be performed by qualified practitioners, not only adequately trained, but who also adhere to safe and clean practice guidelines are essential requirements, and continuing vigilance is required to ensure that acupuncture is safe and is seen to be safe. Future case reports and clinical trials should provide more details on acupuncture related adverse events. For example, the following items should be fully reported: the position of the patient during acupuncture, the targeted acupoints, the characteristic of the practitioner, and the outcome of adverse events. *The guidelines for Case Reports of Adverse Events Related to Acupuncture* [46] could be considered as a guide when reporting adverse events in case reports. Similarly, safety assessment as an important outcome measure should be included in acupuncture associated clinical trials, and related international guidelines such as the *CONSORT for Harms Data Recommendations* [17] should be followed to report and analyse acupuncture related adverse events.

6. Conclusion

Acupuncture has been increasingly practiced in Australia as a complementary and alternative therapy. Its tremendous popularity in Australia over the last 20 years demands continual safety assessment. This review provides an evaluation of the incidence and severity of adverse events reported for acupuncture in Australia between 2012 and 2018. Across 8 databases, fifteen clinical trials and two case reports with a total of 1160 participants receiving true acupuncture treatment were included in this review.

Our findings suggest that acupuncture practice in Australia is well regulated with a better outcome—there were no serious adverse events identified in this review. Acupuncture is generally a safe modality and serious adverse events after treatment are uncommon when supported with well-established guidelines, practiced among licensed, qualified practitioners.

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